UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,500	03/11/2005	Jesus G Valenzuela	4239-66903-02	9994

36218 7590 06/24/2009

KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,500	VALENZUELA ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,25,27-33,35,36 and 80-98* is/are pending in the application.

4a) Of the above claim(s) *27-33,35,36 and 82-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,25,80,81 and 95-98* is/are rejected.

7)☒ Claim(s) *27,33,35,36 and 82-88* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 4-7-09. Claims 2-5, 25, 27-33, 35-36, 80-98 are pending. Claims 2-4 have been amended. Claims 27-33, 35-36, and 82-94 have been withdrawn from consideration. Claims 90-98 are new. Claims 2-5, 25, 80-81, and 95-98 are under examination.

Election Restriction

2. Newly submitted claims 90-94 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has elected invention on 8/15/2007 and the instant application has been examined.
Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 90-94 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. A complete action on all claims to the elected invention should be given.

Rejections Withdrawn

3. In view of the Applicant's amendment and remark following rejections are withdrawn.

a) Rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Jacobs et al WO9920644 Date April 29, 1999 is withdrawn in light of applicant's amendment.

b) Objection to the numbering of claims not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution, whereby claim 89 was missing is withdrawn in light of applicant's amendment.

c) Rejection of claims 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's amendment.

d) Rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment.

e) Rejection of claims 3-4 under 35 U.S.C. 102(b) as being anticipated by Jacobs et al WO9920644 Date April 29, 1999 is withdrawn in light of applicant's amendment.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 5, 95-96, and 98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention are maintained for the reasons set forth in the previous office action in the rejection of claims 2-3, 25, and 81.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112, first paragraph, April 7, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicants state to advance prosecution in this case, claim 2, part (a) is amended to recite "the amino acid sequence set forth as SEQ ID NO: 11", as suggested by the Examiner on page 12 of the Office action and claim 2, part (b) is amended to be directed to "an amino acid sequence at least 98% identical to the amino acid sequence set forth as SEQ ID NO: 11". Applicants state to advance prosecution in this case, claims 3-4 are amended to recite "the amino acid sequence set forth as SEQ ID NO: 11" and claim 3 is amended to be directed to "an amino acid sequence at least 98% identical to the amino acid sequence set forth as SEQ ID NO: 11". Applicants state written description of polypeptides comprising at least 98% sequence identity to SEQ ID NO: 11 (specification, for example, at page 22, lines 21-23; page 35, lines 24-27) and written description

of immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11 (for example, at page 36, lines 5-7 and page 67, lines 3-4). Applicants state as the specification provides guidance regarding conservative amino acid substitutions, the specification clearly identifies which residue substitutions can be accomplished without loss of immunogenicity and an amino acid sequence having at least 98% sequence identity to SEQ ID NO: 11 has a maximum of only six amino acid substitutions and such polypeptide variants would be readily identified by one of ordinary skill in the art. Applicants state as tools to identify immunogenic epitopes of known sequences were well known and readily available at the time the application was filed (for example, Singh and Raghava, Bioinformatics, 17(12): 1236-1237, 2001), immunogenic fragments comprising "at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11" which elicit an immune response would easily have been identified by one of ordinary skill in the art.

Examiner's Response to Applicant's Arguments:

In response to Applicant's statement as set forth supra, the instant claims are drawn to a substantially purified salivary P. *ariasi* polypeptide. Furthermore, in the instant claim step (b) drawn to a vast genus of amino acids of SEQ ID NO: 11 of at least 98% sequence identity and step (c) drawn to a vast genus of an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11 is only a limited number of species disclosed and is not deemed to be representative of the genus encompassed by the instant claims.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of amino acids of SEQ ID NO:11 of at least 98% sequence identity and the genus of an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ

ID NO: 11, applicant must also adequately describe steps (b) and (c) the antigenic determinants (immunoepitopes) that are required for the induction of a directed immune response to specifically bind to an antibody that specifically bind to the amino acid set forth as SEQ ID NO: 11 .The immunogenicity of the polypeptide is not the only functional limitation of the polypeptide. Applicant must also adequately describe variant forms for steps (b) and (c) that are capable of producing an immune response to *P. ariasi*, and additionally also for step (c) the variant forms that specifically binds to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11.

Applicants have only disclosed the following. The SEQ ID NO: 11 known as PRL-P4-E5 (see pgs. 4 and 27). Applicants further disclosed a polynucleotide comprising the sequence of SEQ ID NO: 12, wherein said polynucleotide encodes SEQ ID NO: 11 (see pg. 42). The specification discloses the PRL-P4-E5 mature protein is 290 amino acids long (23-312 of SEQ ID NO: 11) and is encoded by the nucleic acid sequence 91-960 of SEQ ID NO: 12 (see pg. 67).

The data indicated does not correlate to the claimed functions set forth in the instant claims. The specification does not disclose written description of polypeptides comprising at least 98% and 99% sequence identity to SEQ ID NO: 11 wherein the specification discloses which residue substitutions can be accomplished without loss of immunogenicity nor an amino acid sequence having at least 98% and 99% sequence identity to SEQ ID NO: 11 with a maximum of only six amino acid substitutions as stated by Applicant disclosed in the specification (see specification, for example, at page 22, lines 21-23; page 35, lines 24-27). Furthermore, the specification does not disclose distinguishing and identifying features of a representative member of the genus of the amino acids of SEQ ID NO: 11 of at least 98% 99% sequence identity to which the claims are drawn, such as a correlation between structure of the polypeptide and variants thereof and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of polypeptide. Also the specification has not shown that an immunogenic fragment specifically binds to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11 as instantly claimed.

Even though the specification specifically discloses SEQ ID NO: 11 as being a purified salivary *P. ariasi* polypeptide, the polypeptide have not been identified. The specification does not disclose any information on the immunoepitopes which required for the induction of a directed immune response. As a result Applicant has not shown the correlation of the antigenic determinants (immunoepitopes) of SEQ ID NO: 11 with the function to specifically bind to an antibody that can specifically bind to the amino acid set forth as SEQ ID NO: 11.

Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus aforementioned above.

As outlined previously, the claims are drawn to a substantially purified salivary P. ariasi polypeptide, wherein the polypeptide comprises: a) the amino acid sequence set forth as SEQ ID NO: 11; b) an amino acid sequence at least 98% identical to the amino acid sequence set forth as SEQ ID NO: 11; or c) an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, that specifically binds to an, antibody that specifically binds the amino acid sequence set forth as SEQ ID NO: 11, wherein administration of the polypeptide to a subject produces an immune response to P. ariasi (claim 2), wherein the polypeptide comprises an amino acid sequence at least 99% identical to the amino acid sequence set forth as SEQ ID NO: 11 (claim 96), wherein the immunogenic fragment comprises residues 23-312 of SEQ ID NO:11 (claim 98); a substantially purified salivary P. ariasi polypeptide, wherein the polypeptide comprises an amino acid sequence at least 98% identical to the amino acid sequence as set forth as SEQ ID NO:11, wherein administration of the polypeptide to a subject produces an immune response to *P. ariasi* (claim 3), wherein the polypeptide comprises an amino acid sequence at least 99% identical to the amino acid sequence set forth as SEQ ID NO: 11 (claim 95); an immunogenic composition comprising an effective

amount of the polypeptide and a pharmaceutically acceptable carrier (claim 25); an immunogenic composition comprising an effective amount of the polypeptide and a pharmaceutically acceptable carrier (claim 81);

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The independent claims 2-5 and dependent claims 25, 81, 95-96, and 98 are drawn to a vast genus of amino acids of SEQ ID NO: 11 of at least 98% and 99% sequence identity and are drawn to a vast genus of an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of amino acids of SEQ ID NO:11 of at least 98% and 99% sequence identity and the genus of an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, applicant must also adequately describe the antigenic determinants (immunoepitopes) required for the induction of a directed immune response that specifically binds to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11. The immunogenicity of the polypeptide is not the only functional limitation of the polypeptide. Applicant must also adequately describe variant forms capable of producing an immune response to *P. ariasi*, and the variant forms that specifically binds to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11.

Applicants have only disclosed the following: The SEQ ID NO: 11 known as PRL-P4-E5 (see pgs. 4 and 27). Applicants further disclosed a polynucleotide comprising the sequence of

SEQ ID NO: 12, wherein said polynucleotide encodes SEQ ID NO: 11 (see pg. 42).The specification discloses the PRL-P4-E5 mature protein is 290 amino acids long (23-312 of SEQ ID NO: 11) and is encoded by the nucleic acid sequence 91-960 of SEQ ID NO: 12 (see pg. 67).

The data indicated does not correlate to the claimed functions set forth in the instant claims. The specification does not disclose written description of polypeptides comprising at least 98% and 99% sequence identity to SEQ ID NO: 11 wherein the specification discloses which residue substitutions can be accomplished without loss of immunogenicity nor an amino acid sequence having at least 98% and 99% sequence identity to SEQ ID NO: 11 with a maximum of only six amino acid substitutions as stated by Applicant disclosed in the specification (see specification, for example, at page 22, lines 21-23; page 35, lines 24-27). Furthermore, the specification does not disclose distinguishing and identifying features of a representative member of the genus of the amino acids of SEQ ID NO: 11 of at least 98% 99% sequence identity to which the claims are drawn, such as a correlation between structure of the polypeptide and variants thereof and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of polypeptide. Also the specification has not shown that an immunogenic fragment specifically binds to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11 as instantly claimed.

Even though the specification specifically discloses SEQ ID NO: 11 as being a purified salivary *P. ariasi* polypeptide, the polypeptide have not been identified. The specification does not disclose any information on the immunoepitopes which required for the induction of a directed immune response. As a result Applicant has not shown the correlation of the antigenic determinants (immunoepitopes) of SEQ ID NO: 11 with the function to specifically bind to an antibody that can specifically bind to the amino acid set forth as SEQ ID NO: 11. As a result Applicant has not shown the correlation of SEQ ID NO: 11 (or any fragment) with the function as directed with the aforementioned above, given that the polypeptide is not identified and there is no correlation that can be made.

Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential

amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus aforementioned above.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show

that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* **7**: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Furthermore the specification lacks written description of the instant variants that specifically bind to an epitope that specifically bound by an antibody. For example, Colman et al. (Research in Immunology 145: 33-36, 1994, p.33 column 2, p. 35 column 1) disclose that a single amino acid changes in an antigen can effectively abolish the interaction with an antibody entirely and that a very conservative amino acid substitution may abolish antibody binding and a non-conservative amino substitution may have little effect in antibody binding. This underlies the importance of the description of the immunoepitopes that are protective and which conservative amino acid substitutions and where and how many changes can the immunoepitopes tolerate and still retain the ability to protect from infection.

Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the

claimed subject matter would be the same as that of a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of amino acids of SEQ ID NO: 11 of at least 98% and 99% sequence identity and a genus of an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11 with the claimed characteristics, the skilled artisan could not immediately recognize or distinguish members of the claimed genus aforementioned above and variants thereof that are capable of producing an immune response to *P. ariasi* and the capability of specifically binding to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus aforementioned above capable of producing an immune response to *P. ariasi* and the capability of specifically binding to an antibody that specifically binds the amino acid set forth as SEQ ID NO: 11, to which the claims refer. Hence, none of the claims rejected meet the written description requirements.

New Grounds of Objections

5. Claims 27, 33, 35-36, and 82-88 have a status identifier as (Withdrawn and previously presented) after each claim number aforementioned above which is unclear if the claim are withdrawn or either previously presented. Therefore the amendment does not comply with C.F.R. 1.121. Claims 27, 33, 35-36, and 82-89 have been withdrawn from consideration as being directed to a non-elected invention as stated in the Office Action dated 10/9/2007 and 5/29/2008.

All amendments filed must comply with 37 CFR 1.121. Therefore after each claim number, the status identifier of the claim must be presented in a parenthetical expression (for ex.

(original), (currently amended), (previously presented), (canceled), (withdrawn), (new), (not entered) or (withdrawn - currently amended), and the text of each claim under examination as well as all withdrawn claims (each with markings if any, to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application. The appropriate correction to the claims is advised in order further prosecution or else the Office will have to notify applicants via a Notice of Non-Compliant Amendment in future correspondence.

6. Claim 80 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 80 is drawn to a substantially purified salivary P. ariasi polypeptide according to claim 4, wherein the polypeptide consists of an amino acid sequence set forth as SEQ ID NO: 11 does not further limit the parent claim 4. Therefore, claim 80 as depending from claim 4, is not further limiting.

7. Claims 2-3, and 5 and all dependent claims 4, 80, and 95-97 objected to because of the following informalities: As to independent claims 2-3, and 5 and all dependent claims 4, 80, and 95-97, the claims recite the phrase "set forth as". The claim language is unclear. Amendment of the claims to add the word "of" would obviate this issue. Appropriate correction is required.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 4 and 80 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment.

As to claims 4 and 80 dependent claim, the claims are inconsistent, claim 4 is drawn to a *P. ariasi* polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 11 which requires all of SEQ ID NO:11 to be present, whereas further limiting claim 80 is drawn to *P. ariasi* polypeptide, wherein the polypeptide consist of an amino acid sequence set forth as SEQ ID NO: 11 to present which requires two contiguous amino acids of SEQ ID NO:11 to be present. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of the instant claims 4 and 80, nor how to assess such.

Conclusion

9. No claims allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645